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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,146	06/27/2003	Alfred W. Prais	4133-030915 (P-5532/2P1)	6718
26253	7590	11/03/2006	EXAMINER	
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			DESANTO, MATTHEW F	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/609,146

Applicant(s)

PRAIS ET AL.

Examiner

Matthew F. DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/03/03, 12/09/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species F in the reply filed on 7/28/06 is acknowledged.

Priority

The later-filed application must be an application for a patent for an invention, which is also disclosed, in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/141,114, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. All the claims lack support from the CIP because of the embodiment chosen (Figures 23-31) since the collar holds the needle; the projection element (250) also lacks support from the CIP. Therefore the date being used is the filing date of this case, which is 6/27/03.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 7-12, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newby et al. (USPN 6,298,541) and further in view of Rubin (USPN 3194237) or Steiner (USPN 3948261).

Newby et al. discloses a shieldable unit dose having a shield (140) in pivotal engagement with a needle, a collar (90 & 60) including a needle end, and a needle holding member (300,302) handle extending from said collar opposite said needle end as well as all the further limitations of the dependent claims, but Newby et al. fails to disclose wherein the needle end is a unit dose with a bifurcated needle, wherein the prong end includes two pointed prongs and form a U-shaped channel for maintaining a liquid vaccine within the channel.

B. A. Rubin discloses a unit dose with a bifurcated needle, wherein the prong end includes two pointed prongs (Columns 1 and 2).

Steiner discloses a unit dose with a bifurcated needle, wherein the prong end includes two pointed prongs (Columns 1 and 2).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Newby et al. with Cowan or Steiner teachings of using a bifurcated needle, wherein the prong end includes two pointed prongs to introduce a fluid into the body, because it is well known in the art to use a bifurcated needle to introduce a vaccine or fluid because the bifurcations allows for easier insertion into the patient as well as a channel to allow the "liquid" to be maintained. It is also well known in the art to change the needles of syringes depending on the intended application such as vaccination or applying fibrin adhesive to the body. The needles taught by Steiner

and Rubin are more effective for introducing vaccines through the skin, therefore it would be obvious to use those needles when introducing vaccines, as opposed to regular hollow needles.

4. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney et al. (USPN 5868716), and further in view of Rubin (USPN 3194237) or Steiner (USPN 3948261).

Sweeney et al. discloses a shieldable unit dose having a shield (36a) in pivotal engagement with a needle, a collar (52a) including a needle end, and a needle holding member (12) extending from said collar opposite said needle end, and a projection member (60) as well as all the further limitations of the dependent claims, but Sweeney et al. fails to disclose wherein the needle end is a unit dose with a bifurcated needle, wherein the prong end includes two pointed prongs and form a U-shaped channel for maintaining a liquid vaccine within the channel. (Entire reference)

B. A. Rubin discloses a unit dose with a bifurcated needle, wherein the prong end includes two pointed prongs (Columns 1 and 2).

Steiner discloses a unit dose with a bifurcated needle, wherein the prong end includes two pointed prongs (Columns 1 and 2).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Sweeney et al. with Rubin or Steiner (since Rubin or Steiner teach the use of a bifurcated needle, wherein the prong end includes two pointed prongs to introduce a fluid into the body), because it is well known in the art to use a bifurcated needle, with a prong end that includes two pointed prongs to introduce

fluid into the body since the vaccine or fluid is held in place between the two prongs thus allowing easy insertion into the body by the pointed prongs. It is also well known in the art to change the needles of syringes depending on the intended application such as vaccination or applying fibrin adhesive to the body. The needles taught by Steiner and Rubin are more effective for introducing vaccines through the skin, therefore it would be obvious to use those needles when introducing vaccines, as opposed to regular hollow needles.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Matthew DeSanto
Art Unit 3763
October 30, 2006